

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

In re Rivastigmine Patent Litigation

Consolidation of:

MDL No. 1661  
(Transferred to this District for  
pre-trial purposes from the  
Central District of California)

NOVARTIS PHARMACEUTICALS  
CORPORATION, NOVARTIS AG,  
NOVARTIS PHARMA AG, NOVARTIS  
INTERNATIONAL PHARMACEUTICAL  
LTD., and PROTERRA AG,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD. and  
DR. REDDY'S LABORATORIES, INC.,

Defendants.

Civil Action No.:  
04-CV-06045-HB

NOVARTIS PHARMACEUTICALS  
CORPORATION, NOVARTIS AG,  
NOVARTIS PHARMA AG, NOVARTIS  
INTERNATIONAL PHARMACEUTICAL  
LTD., and PROTERRA AG,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC. and  
WATSON LABORATORIES, INC.,

Defendants.

Civil Action No.:  
05-CV-02234-HB

Civil Action No.:  
04-CV-07594-MRP-CT

NOVARTIS PHARMACEUTICALS  
CORPORATION, NOVARTIS AG,  
NOVARTIS PHARMA AG, NOVARTIS  
INTERNATIONAL PHARMACEUTICAL  
LTD., and PROTERRA AG,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD

Defendants.

Civil Action No.:  
05-CV-02235-HB

**WATSON'S ANSWER AND COUNTERCLAIMS  
TO AMENDED COMPLAINT**

Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively, “Watson”), as their Answer to each of the numbered paragraphs in the Amended Complaint for Patent Infringement by Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and Proterra AG, respond and allege as follows:

### **NATURE OF ACTION**

1. With respect to paragraph 1, Watson admits that the Complaint purports to state a cause of action for patent infringement, but denies that the Complaint states such a cause of action and denies that Watson has committed or will commit any acts giving rise to such a cause of action.

### **PARTIES**

2. Watson is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and, therefore, denies the allegations.

3. Watson is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and, therefore, denies the allegations.

4. Watson is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 and, therefore, denies the allegations.

5. Watson is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 and, therefore, denies the allegations.

6. Watson is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 and, therefore, denies the allegations.

7. Defendant Watson Pharmaceuticals, Inc. denies the allegations in paragraph 7.

8. Defendant Watson Laboratories, Inc. admits the allegations in paragraph 8.

9. Watson admits the allegations in paragraph 9.

10. Watson admits that certain officers and directors are common to Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc., but to the extent that it alleges that all officers and directors are common to both entities, paragraph 10 is denied.

11. Watson denies the allegations of paragraph 11.

12. Paragraph 12 merely defines a term and contains no averment of fact that could be denied or admitted; but to the extent it is asserted to contain such an averment, paragraph 12 is denied.

### **JURISDICTION AND VENUE**

13. Watson denies the allegations in paragraph 13. Furthermore, subject matter jurisdiction is a question of law to which no response is required.

14. Plaintiffs sought specific leave from the Court, which was granted by order dated April 25, 2005, to amend the complaint to add certain inducement allegations. Plaintiffs have not sought, and were not granted, leave to amend the Complaint to add allegations concerning any alleged independent ground for jurisdiction and venue in this District and such allegations are unnecessary under 28 U.S.C. § 1407. Accordingly, this paragraph was amended in violation of Fed. R. Civ. P. 15(a), and no response is required.

15. Plaintiffs sought specific leave from the Court, which was granted by order dated April 25, 2005, to amend the complaint to add certain inducement allegations. Plaintiffs have not sought, and were not granted, leave to amend the Complaint to add allegations concerning any alleged independent ground for jurisdiction and venue in this District and such allegations are unnecessary under 28 U.S.C. § 1407. Accordingly, this paragraph was amended in violation of Fed. R. Civ. P. 15(a), and no response is required.

### **CLAIM FOR RELIEF – PATENT INFRINGEMENT**

16. With respect to paragraph 16, Watson admits that Novartis Pharmaceuticals Corporation has been identified by the United States Food and Drug Administration (“FDA”) as

the holder of New Drug Application (“NDA”) No. 20-823 for Exelon<sup>®</sup> capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg). Watson further admits that rivastigmine tartrate has been identified by the FDA as the active ingredient in Exelon<sup>®</sup> capsules. Watson is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 and, therefore, denies the allegations.

17. Watson admits the allegations in paragraph 17.

18. With respect to paragraph 18, Watson admits only that United States Patent No. 4,948,807 (“the ‘807 patent”) on its face identifies Plaintiff Proterra AG as the assignee. Watson is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies the allegations. Watson specifically denies that the ‘807 patent was duly and legally issued.

19. With respect to paragraph 19, Watson admits only that what appears to be a true and correct copy of the ‘807 patent is attached to the Complaint as Exhibit A. Watson denies the remaining allegations in paragraph 19. Furthermore, the proper scope of a patent claim is a conclusion of law to which no response is required.

20. Watson is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 and, therefore, denies the allegations. Watson specifically denies that United States Patent No. 5,602,176 (“the ‘176 patent”) was duly and legally issued.

21. Watson is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 and, therefore, denies the allegations.

22. With respect to paragraph 22, Watson admits only that what appears to be a true and correct copy of the ‘176 patent is attached to the Complaint as Exhibit B. Watson denies the remaining allegations in paragraph 22. Furthermore, the proper scope of a patent claim is a conclusion of law to which no response is required.

23. With respect to paragraph 23, Watson admits only that Defendant Watson Laboratories, Inc. has submitted an Abbreviated New Drug Application (“ANDA”) to the FDA for rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg). Watson denies the remaining allegations in paragraph 23.

24. Watson admits the allegations in paragraph 24.

25. With respect to paragraph 25, Watson admits that 35 U.S.C. § 271 (e)(2) creates a statutory, technical act of infringement to support subject matter jurisdiction. Watson denies the remaining allegations in paragraph 25, and specifically denies that Watson’s proposed rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) that are the subject of Watson’s ANDA would, if marketed, infringe any valid and enforceable claim of either the ‘807 patent or the ‘176 patent.

26. Watson denies the allegations in paragraph 26.

27. Watson admits the allegations in paragraph 27.

28. Watson denies the allegations in paragraph 28.

29. Watson denies the allegations in paragraph 29.

30. With respect to paragraph 30, Watson admits that 35 U.S.C. § 271 (e)(2) creates a statutory, technical act of infringement to support subject matter jurisdiction. Watson denies the remaining allegations in paragraph 30, and specifically denies that Watson’s proposed rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) that are the subject of Watson’s ANDA would, if marketed, infringe any valid and enforceable claim of either the ‘807 patent or the ‘176 patent.

### **DEFENSES**

31. Without any admission as to burden of proof, Watson states the following defenses:

**FIRST DEFENSE**

**FAILURE TO STATE A CLAIM**

32. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

**SECOND DEFENSE**

**NON-INFRINGEMENT OF UNITED STATES PATENT NO. 4,948,807**

33. Watson's proposed rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) that are the subject of Watson's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '807 patent.

**THIRD DEFENSE**

**INVALIDITY OF UNITED STATES PATENT NO. 4,948,807**

34. The '807 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 102, 103 and/or 112.

**FOURTH DEFENSE**

**UNENFORCEABILITY OF UNITED STATES PATENT NO. 4,948,807  
DUE TO INEQUITABLE CONDUCT**

35. The '807 patent is unenforceable because during its prosecution the named inventors Marta W. Rosin (a.k.a. Marta Weinstock), Michael Chorev and Zeev Tashma (collectively "Applicants"), and their patent prosecution attorneys at the firm of Laughlin, Markensohn, Lagani & Pegg, engaged in inequitable conduct and breach of the duty of candor required by 37 C.F.R. § 1.56.

36. The '807 patent issued from U.S. Patent Application Serial No. 320,700, which is a continuation of U.S. Application Serial No. 185,451 ("the '451 Application"), which in turn is a continuation of U.S. Application Serial No. 835,466, which claims priority date of March 5, 1985, based on Israeli patent application number 74,497 (collectively "the Applications").

37. On February 22, 1989, the Examiner held an interview with attorney Horst Kasper to discuss Claim 18 of the '451 Application. On information and belief, Horst Kasper was associated with the firm of Laughlin, Markensohn, Lagani & Pegg.

38. Claim 18 of the '451 Application claims a substance referred to in the Applications as "RA7". RA7 has –ethyl, –methyl substitution on the carbamate group. Claim 18 matured into Claim 3 of the '807 patent.

39. The Examiner's Interview Summary Record stated: "A comparison of Claim 18 should be with closest prior art compounds; however, further evidence not already of record probably would not be considered in this case."

40. In an Amendment dated February 28, 1989, Mr. Kasper stated: "It was noted during the interview that the closest art of record appeared to be the compound code 1207 on page 177, first item of Table V of the journal article 'Insecticidal Activity of Substituted Phenyl N-Methylcarbamates' by J. Meltzer and H.B.A. Welle...".

41. Compound code 1207 is known as and referred to in the Applications as miotine. Miotine is similar to RA7, but has –hydrogen, –methyl substitution on the carbamate group.

42. The February 28, 1989 Amendment further pointed out superiority of RA7 compared to miotine respecting pharmacokinetic parameters such as potency, toxicity, duration and therapeutic ratio.

43. The Examiner allowed Claim 18 on March 14, 1989 without further rejection.

44. Table V of the Meltzer article also teaches compound code 1261, just below miotine. Compound 1261 was referred to during prosecution as "the Meltzer compound", and referred to in the Applications as "RA10".

45. The Meltzer compound is a homologue to RA7, with –methyl, –methyl substitution on the carbamate group. Therefore the Meltzer compound is structurally the closest art compound. Data in the Applications show that the Meltzer compound is also the closest art of

record in terms of pharmacokinetic parameters such as potency, toxicity, duration and therapeutic ratio. As the closest prior art, the Meltzer compound is clearly material to the issue of RA7's patentability.

46. The Meltzer compound rendered RA7 prima facie obvious, and data in the Applications show that RA7's therapeutic properties are not unexpected in view of the Meltzer compound. The differences in RA7's therapeutic properties are more pronounced and arguably patentable only when compared to miotine.

47. The Amendment dated February 28, 1989 makes no mention of the Meltzer compound. Applicants and their attorneys affirmatively misrepresented miotine as the closest art of record in order to obtain allowance of Claim 18. Applicant's purposeful withholding of the most relevant and material prior art in their possession, coupled with their misleading proffer of miotine as the most relevant prior art, evidences and demonstrates Applicants' intent to deceive.

48. The duty of candor and disclosure requires, inter alia, Applicants, their agents and/or attorneys, and anyone else substantively involved in prosecuting the application to disclose all information that a reasonable examiner reviewing the application would consider important in determining whether to allow the proposed claims to issue.

49. Applicants breached their duty of candor and good faith dealing mandated by 37 C.F.R. § 1.56 by not submitting a single prior art reference with the patent applications.

50. Applicants attached two prior art references by Stedman and Stedman in a letter dated April 21, 1989, only after the Examiner allowed Claim 18. As the Examiner stated in an Office Action dated May 24, 1989, the submission was untimely and without the requisite explanations required by M.P.E.P. 609, 37 C.F.R. 1.131 or 37 C.F.R. 1.56 (a). The Examiner stated, "Applicant is advised that the filing of the above-noted paper may not satisfy the duty of disclosure requirement of 37 CFR 1.56 insofar as any material information is referenced in the [submission]".



51. Applicants and their attorneys also did not disclose additional prior art that was material to the patentability of the '807 patent: an article by J. P. Long, Structure-Activity Relationships of the Reversible Anticholinesterase Agents, in Handbuch der Experimentellen Pharmakologie (George B. Koelle ed., 1963). Applicants stated that chemical instability of physostigmine, the reference drug, is one of the problems they sought to overcome. The Long article reported that dialkylated phenylcarbamate, such as the Meltzer compound and RA7, are stable compared to physostigmine or miotine, and highly active. Applicants withheld this prior art from the U.S. Patent and Trademark Office, materially misrepresenting the state of the art to that Office.

52. The Examiner would not have allowed claims drawn to RA7 had he been directed to note the properties of the Meltzer compound. Applicants and their attorneys at Laughlin, Markensohn, Lagani & Pegg affirmatively misrepresented material facts and took advantage of the Examiner's oversight and lack of knowledge to obtain the '807 patent claiming RA7, which is not patentable because it is, inter alia, obvious under 35 U.S.C. § 103.

53. Given the highly material nature of these misrepresentations, Applicants' intent to mislead the PTO can be inferred. Additional evidence developed in discovery will further demonstrate the Applicants' intent to mislead.

#### **FIFTH DEFENSE**

##### **NON-INFRINGEMENT OF UNITED STATES PATENT NO. 5,602,176**

54. Watson's proposed rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) that are the subject of Watson's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '176 patent.

**SIXTH DEFENSE**

**INVALIDITY OF UNITED STATES PATENT NO. 5,602,176**

55. The '176 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 102, 103 and/or 112 and under the doctrine of obviousness-type double patenting.

**SEVENTH DEFENSE**

**UNENFORCEABILITY OF UNITED STATES PATENT NO. 5,602,176  
DUE TO PROSECUTION HISTORY LACHES**

56. The '176 patent and the claims thereof are unenforceable due to unreasonable and unexplained delay in prosecuting the applications that resulted in the '176 patent.

**EIGHTH DEFENSE**

**ADDITIONAL DEFENSES AND COUNTERCLAIMS**

57. Watson reserves the right to assert any additional defenses or counterclaims that discovery may reveal.

**COUNTERCLAIMS**

58. Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively, "Watson") bring the following Counterclaims against Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and Proterra AG (collectively, "Counterdefendants").

**JURISDICTION AND VENUE**

59. This is an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Patent Laws of the United States, and 21 U.S.C. § 355(c)(3)(D)(ii), based upon an actual controversy between the parties to declare that Watson is free to continue to seek approval of Watson's Abbreviated New Drug Application ("ANDA"), and upon approval by the FDA, to manufacture, use, market, sell, and offer to sell its rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) as described in said ANDA in the United States. This Court has jurisdiction of the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

60. Venue is proper under 28 U.S.C. §§ 1391 and 1400, and by Counterdefendants' choice of forum.

### **PARTIES**

61. Counterclaimant Watson Pharmaceuticals, Inc. is a Nevada corporation with a principal place of business at 311 Bonnie Circle, Corona, California 92880.

62. Counterclaimant Watson Laboratories, Inc. is a Nevada corporation with a principal place of business at 311 Bonnie Circle, Corona, California 92880.

63. On information and belief, Counterdefendant Novartis Pharmaceuticals Corporation is a Delaware corporation having its principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

64. On information and belief, Counterdefendant Novartis AG is a Swiss corporation having its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

65. On information and belief, Counterdefendant Novartis Pharma AG is a Swiss corporation having its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

66. On information and belief, Counterdefendant Novartis International Pharmaceutical Ltd. is a Bermuda corporation having its principal place of business at Hurst Holme, 12 Trott Road, Hamilton HM 11, Bermuda.

67. On information and belief, Counterdefendant Proterra AG is a Swiss corporation having a place of business at Poststrasse 9, CH-6300 Zug, Switzerland.

### **FIRST COUNTERCLAIM**

#### **ORDER OF DELETION OF UNITED STATES PATENT NO. 4,948,807 FROM PATENT INFORMATION FOR NOVARTIS PHARMACEUTICAL CORP.'S NEW DRUG APPLICATION NO. 20-823**

68. Watson incorporates by reference and re-alleges each of the allegations set forth in paragraphs 1 through 67.

69. Because United States Patent No. 4,948,807 (“the ‘807 patent”) does not claim the drug for which the Counterdefendant Novartis Pharmaceuticals Corporation’s NDA No. 20-823 was approved, an order requiring Counterdefendant Novartis Pharmaceuticals Corporation to delete the ‘807 patent from patent information submitted for NDA No. 20-823 is necessary and appropriate under 21 U.S.C. § 355(c)(3)(D)(ii).

### **SECOND COUNTERCLAIM**

#### **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF UNITED STATES PATENT NO.4,948,807**

70. Watson incorporates by reference and re-alleges each of the allegations set forth in paragraphs 1 through 67.

71. Watson’s rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) that is the subject of its ANDA has not infringed, and would not, if marketed, infringe any valid and enforceable claim of the ‘807 patent.

72. Because Counterdefendants maintain this action that Watson’s filing of an ANDA for approval to market rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) infringes the ‘807 patent, a declaration of rights between the parties is both appropriate and necessary to establish that Watson has not infringed and does not infringe the ‘807 patent.

### **THIRD COUNTERCLAIM**

#### **DECLARATORY JUDGMENT OF INVALIDITY AND/OR UNENFORCEABILITY OF UNITED STATES PATENT NO. 4,948,807**

73. Watson incorporates by reference and re-alleges each of the allegations set forth in paragraphs 1 through 67.

74. Because Counterdefendants maintain and Watson denies that the ‘807 patent and the claims thereof are valid and enforceable, a declaration is both appropriate and necessary to establish that the ‘807 patent and the claims thereof are invalid and/or unenforceable under one or more of 35 U.S.C. §§ 102, 103, 112, 282 and/or 37 C.F.R. § 1.56.

**FOURTH COUNTERCLAIM**

**DECLARATORY JUDGMENT OF NONINFRINGEMENT OF  
UNITED STATES PATENT NO. 5,602,176**

75. Watson incorporates by reference and re-alleges each of the allegations set forth in paragraphs 1 through 67.

76. Watson's rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) that is the subject of their ANDA has not infringed, and would not, if marketed, infringe any valid and enforceable claim of United States Patent No. 5,602,176 ("the '176 patent").

77. Because Counterdefendants maintain this action that Watson's filing of an ANDA for approval to market rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5mg and 6 mg) infringes the '176 patent, a declaration of rights between the parties is both appropriate and necessary to establish that Watson has not infringed and does not infringe any valid and enforceable claim of the '176 patent.

**FIFTH COUNTERCLAIM**

**DECLARATORY JUDGMENT OF INVALIDITY AND/OR UNENFORCEABILITY  
OF UNITED STATES PATENT NO. 5,602,176**

78. Watson incorporates by reference and re-alleges each of the allegations set forth in paragraphs 1 through 67.

79. Because Counterdefendants maintain and Watson denies that the '176 patent and the claims thereof are valid and enforceable, a declaration is both appropriate and necessary to establish that the '176 patents and the claims thereof are invalid and/or unenforceable under one or more of 35 U.S.C. §§ 102, 103, 112, 282, 37 C.F.R. § 1.56, the doctrines of obviousness-type double patenting, and prosecution history laches.

**RELIEF REQUESTED**

WHEREFORE, Watson respectfully requests that this Court enter judgment as follows:

A. That all claims against Watson be dismissed with prejudice and that all relief requested by Plaintiffs/Counterdefendants be denied;

B. That Watson has not infringed and do not infringe any valid and enforceable claim of the '807 and '176 patents and has a lawful right to proceed with its ANDA for approval to market rivastigmine tartrate capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) and further has a lawful right to manufacture, market and sell the rivastigmine tartrate capsules once approved by the FDA;

C. That Plaintiff Novartis Pharmaceutical Corporation's New Drug Application No. 20-823 inappropriately identifies the '807 patent as claiming rivastigmine tartrate, the active pharmaceutical ingredient in Exelon<sup>®</sup> capsules;

D. That the '807 and '176 patents are invalid and/or unenforceable;

E. That the 30-month time period under 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately;

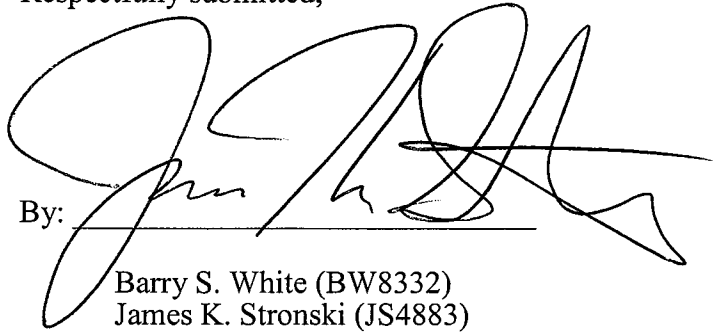
F. That Plaintiffs/Counterdefendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who received actual notice thereof, be preliminarily and permanently enjoined from initiating infringement litigation against, or threatening Watson or any parties associated therewith (including Watson's customers) or charging any of them either orally or in writing with infringement of the patents in suit;

G. That the inequitable conduct and breach of the duty of candor in prosecution of the Applications for the '807 patent makes this action an exceptional case under 35 U.S.C. § 285, and that Watson is, therefore, entitled to an award of its attorney's fees, costs and expenses in this action; and

H. That Watson be awarded such other and further relief as this Court may deem just and proper.

Dated: May 25, 2005

Respectfully submitted,

By: 

Barry S. White (BW8332)  
James K. Stronski (JS4883)  
Kimberly J. McGraw (KM4676)  
H. Sarah Park (HS0659)

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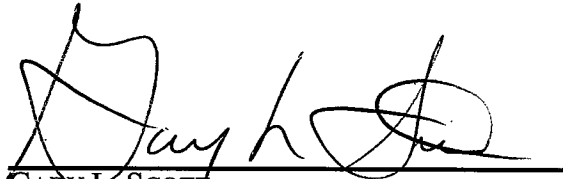
Attorney for Defendants/Counterclaimants  
Watson Pharmaceuticals, Inc. and  
Watson Laboratories, Inc.

**CERTIFICATE OF SERVICE**

I hereby certify that on this 25th day of May 2005, I caused a true copy of the **Second Amended Answer and Counterclaims of Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc.** to be served upon counsel for Plaintiffs via Federal Express overnight delivery and the District Court's Electronic Filing System (ECF) upon:

Diego Scambia  
FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112

Counsel for Plaintiffs Novartis  
Pharmaceuticals Corporation,  
Novartis AG, Novartis Pharma AG,  
Novartis International  
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